REMARKS

After entry of the amendment, claims 1 to 30 and 32 will remain pending. Claim 31 has been canceled, without prejudice. Claim 1 is amended to clarify that the process obtains modafinil having a granulometry wherein the ratio of median to mean is from 1:3 to 1:0.3 and of median to mode is from 1:3 to 1:0.3. Support for this amendment may be found, for example, at page 7, lines 18 to 23. Claim 7 has been amended to delete the preferred aspect of the claim, which has been re-presented in new claim 32. No new matter is added.

Rejection Under 35 U.S.C. § 112, 2nd Paragraph

Claims 1 to 3 and 5 to 31 stand rejected as allegedly indefinite, apparently because the specification allegedly teaches that the concentration of DMSAM may be a relevant factor in determining granulometry. Applicants respectfully traverse.

At page 5, lines 19-27, the specification teaches that

> "there are three operating parameters which allow the particle size distribution of the end product to be controlled and these are:
>
> - the concentration of the DMSAM used as reactant;
> - the reaction temperature; and
> - the stirring speed.
>
> In practice, one of the three parameters, for example the concentration of the DMSAM solution, is fixed in a first phase and the two other parameters, *i.e.*, the temperature and the stirring speed, are predetermined as a function of the desired granulometry of the modafinil."

The first step of the process as defined in claim 1 consists in preparing a solution of DMSAM in a solvent. This implicitly means that, at the end of step a), the concentration of the DMSAM solution is fixed. The two other parameters (that is, the temperature and the stirring speed) are then predetermined as a function if the desired granulometry of modafinil.

Hence, claim 1 is consistent with the specification and notably, with the cited disclosure. Withdrawal of the rejection is accordingly requested.

Claim 7 also stands rejected under Section 112, second paragraph, based on use of the word "preferably." The preferred aspect has been deleted and moved to new claim 32. Accordingly, this rejection is rendered moot.

Rejection Under 35 U.S.C. § 102

Claims 1 and 31 are alleged to be anticipated by Lafon, U.S. 4,927, 855 and Grebow, et al., U.S. 5,618,845 (against claim 31 only). Applicants traverse the rejection of claim 1. Claim 31 has been canceled, without prejudice, thereby rendering this rejection moot.

Lafon discloses a method for preparing modafinil comprising:

a) preparing a solution of DMSAM in a solvent, namely jethanol;

b) contacting the solution obtained with NH_3 under stirring; and

c) isolating the modafinil formed, notably by evaporating (see col. 3, prep. 1(d).

No mention in made in Lafon relating to the stirring rate and/or temperature, or to the granulometry of the modafinil obtained. Accordingly, Applicants respectfully submit that the document does not affect the novelty of claim 1.

Rejection Under 35 U.S.C. § 103

The Examiner also rejects claims 1-31 as being allegedly unpatentable over the combined teaching of Lafon (US 4,927,855), Grebow et al. (US 5,618,845) in view of Singer et al. (WO 02/10125) and Laurent (US 5,719,168). Applicants respectfully disagree.

Claim 1 relates to a process for preparing modafinil having a defined granulometry wherein the ratio of median to mean is of 1:3 to 1:0.3 and median to mode is of 1:3 to 1:0.3 which comprises the step of:

a) preparing a solution of DMSAM ;

b) contacting the solution obtained with NH3 at a predetermined temperature and a predetermined stirring; and

c) isolating the modafinil formed,

wherein said temperature and said stirring are within specific ranges in order to obtain said defined granulometry.

Lafon would appear to be the closest art. However, Lafon does not specify the granulometry of modafinil particles, nor the stirring rate or the temperature. The difference between Lafon and the present application is thus the predetermination of temperature and stirring speed in view of the desired specific granulometry.

It is known that the particle size of the modafinil has great influence on its pharmacological efficacy. In particular, small modafinil particles induce an increase in the pharmacological efficacy (see p.3 lines 11 to 16 of the specification). The objective technical

problem is thus to provide a process for preparing modafinil particles having a defined and controlled granulometry.

As explained in the present description, presently claimed temperature and stirring speed both determine the desired granulometry (see p. 9 lines 10 and 11 of the specification).

Singer et al. relates to a process for preparing modafinil by oxidizing diphenylmethylthio-2-acetamide with H_20_2. (see examples 1, 2 and 5.) Similarly, Laurent discloses a method for preparing benzhydrylsulfinylacetamide derivatives by oxidizing the corresponding benzhydrylthioacetamide derivatives with H_20_2. These documents do not teach or suggest contacting the solution of DMSAM with NH_3 at a predetermined temperature and stirring. One of ordinary skill in the art, seeking a process for producing modafinil by using NH, will thus not contemplate Singer et al. nor Laurent et al.

Further, the references do not mention nor suggest to control the temperature and stirring speed in view of controlling the modafinil granulometry. Hence, even if one skilled in the art would have contemplated these documents, he would not have been incited to control the temperature and the stirring speed in view of controlling the granulometry or in expectation of improvement or advantage.

Accordingly, Applicants respectfully submit that claim 1 and dependent claims are inventive and nonobvious in view of Lafon, either considered alone or in combination with Singer et al. or Laurent et al. Withdrawal of the rejection is therefore respectfully requested.

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